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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/790,562	03/01/2004	Abraham Bout	2578-4038.3US	2578-4038.3US 9903	
24247 TRASK BRIT	7590 01/11/2008 T		EXAM	INER	
P.O. BOX 2550			JOIKE, MICHELE K		
SALT LAKE CITY, UT 84110			ART UNIT	PAPER NUMBER	
		1636			
			NOTIFICATION DATE	DELIVERY MODE	
			01/11/2008	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

	Application No.	Applicant(s)				
	10/790,562	BOUT ET AL.				
Office Action Summary	Examiner	Art Unit				
	Michele K. Joike, Ph.D.	1636				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period was reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from 1, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 17 O	<u>ctober 2007</u> .					
·—	, —					
• •	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1,7-21 and 25-56</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
_	6)⊠ Claim(s) <u>1, 7-9, 15, 16, 21, 25, 26, 29, 36, 37, 46, 47, 53, 54, 56</u> is/are rejected.					
7) Claim(s) <u>10-14,17-20,27,28,30-35,38-45,48-52 and 55</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list	of the certified copies not receive	ed.				
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> </ol>	4) Interview Summary Paper No(s)/Mail Da					
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	5) Notice of Informal F 6) Other:					

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#### DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed October 17, 2007. Claims 2-6 and 22-24 are canceled. Claims 7 and 25 were amended.

Claims 1, 7-21 and 25-56 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 13, 2007, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous

Office Action and/or sets forth new rejections that are necessitated by amendment, this

Office Action is made FINAL.

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7-9, 15, 21, 25-26, 36, 46 and 53 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 and 29-30 of copending Application No. 11/110,517.

Claims 21, 25-26, 29, 46-47, 53-54 and 56 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 11/271,368.

Claims 1, 7-9, 15-16 and 36-37 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-34 and 37 of copending Application No. 11/450,038.

Claims 21, 25-26, 29, 46-47, 53-54 and 56 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 and 18 of copending Application No. 11/256,352.

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Claims 21, 25-26, 46-47 and 53-54 stand rejected on the ground of nonstatutory double patenting over claims 1-21 of U.S. Patent No. 7,192,759 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

## Response to Arguments Concerning Claim Rejections – Double Patenting

Applicant's arguments filed October 17, 2007 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants had chosen to hold their response in abeyance for co-pending applications 11/110,517, 11/271,368, 11/450,038 and 11/256,352.

Applicants argue that the instant claims teaches integration of the nucleic acid into the cell's genome, and US 7,192,759 does not teach integration, but replication of the nucleic acid in the cells.

These arguments are not found persuasive for the following reasons.

Claim 21, which is dependent on claim 1, does not teach integration of the nucleic acid, specifically. Rather the language of claim 1 is "wherein the recombinant nucleotide sequence in expressible format encoding the protein of interest forms part of the genome of the eukaryotic cell". The language used is broad, and can include, for example, a plasmid that has been introduced into the cell. The nucleic acid does not have to integrate into the genome to be *part* of the cell's genome.

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## Allowable Subject Matter

Claims 10-14, 17-20, 27-28, 30-35, 38-45, 48-52 and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D. Examiner
Art Unit 1636

PRIMARY EXAMINER